



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------------------------------------------------------|-------------|----------------------|--------------------------------|------------------|
| 10/672,067 | 09/29/2003 | Lawrence C. Paoletti | 7570/80639 | 4716 |
| 66991 7590 01/10/2007 LAW OFFICE OF MICHAEL A. SANZO, LLC 15400 CALHOUN DR. SUITE 125 ROCKVILLE, MD 20855 | | | EXAMINER BEISNER, WILLIAM H | |
| | | | ART UNIT 1744 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 01/10/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/672,067 | PAOLETTI ET AL. | |
| | Examiner | Art Unit | |
| | William H. Beisner | 1744 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18-38 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 18-38 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 29 September 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/03 & 10/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 9/29/2003 and 10/19/2006 have been considered and made of record.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 18, 19, 24-27 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Legros et al.(EP 152730).

With respect to claim 18, the reference of Legros et al. discloses a culture apparatus that is structurally the same as that instantly claimed. Specifically the reference discloses a fermentor (1) with an inlet port (4) and an outlet port (10). The device includes a culture vessel (2) with an inlet port (18) which is connected to outlet port (10) of the fermentor (1) and an outlet port (17). The device includes a means (29) for moving fluid from the outlet port (10) of the fermentor (1) to the inlet port (18) of the culture vessel (2).

With respect to claim 19, the device includes means (21) for removing fluid from the outlet port (17) of the culture vessel.

With respect to claims 24 and 38, the culture vessel (2) is a culture flask.

Art Unit: 1744

With respect to claims 25-27, elements (21) and (29) are pumps.

With respect to claims 36 and 37, the fermentor (1) includes a motor driven mixing paddle (7).

4. Claims 18, 25, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Stephanopoulos et al.(US 5,262,320).

With respect to claim 18, the reference of Stephanopoulos et al. discloses a culture apparatus (10) that is structurally the same as that instantly claimed. Specifically the reference discloses a fermentor (32) with an inlet port (66) and an outlet port (46). The device includes a culture vessel (12) with an inlet port (20) which is connected to outlet port (46) of the fermentor (32) and an outlet port (22). The device includes a means (48) for moving fluid from the outlet port (46) of the fermentor (32) to the inlet port (20) of the culture vessel (12).

With respect to claim 25, element (48) is a pump.

With respect to claims 36 and 37, the fermentor (32) includes a motor driven mixing paddle (44).

5. Claims 18, 19, 25-27, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Patton et al.(US 3,338,792).

With respect to claim 18, the reference of Patton et al. discloses a culture apparatus that is structurally the same as that instantly claimed. Specifically the reference discloses a fermentor (11) with an inlet port (12) and an outlet port (21). The device includes a culture vessel (23) with an inlet port which is connected to outlet port (21) of the fermentor (11) and an outlet port (30).

Art Unit: 1744

The device includes a means (22) for moving fluid from the outlet port (21) of the fermentor (11) to the inlet port of the culture vessel (23).

With respect to claim 19, the device includes means (31) for removing fluid from the outlet port (30) of the culture vessel.

With respect to claims 25-27, elements (22) and (31) are pumps.

With respect to claims 36 and 37, the fermentor (11) includes a motor driven mixing paddle (15).

6. Claims 18, 19, 24-27 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Besnainon et al.(US 5,064,764).

With respect to claim 18, the reference of Besnainon et al. discloses a culture apparatus that is structurally the same as that instantly claimed. Specifically the reference discloses a fermentor (18) with an inlet port (22) and an outlet port (38). The device includes a culture vessel (14) with an inlet port (16 or 32) which is connected to outlet port (38) of the fermentor (18) and an outlet port (40). The device includes a means (36) for moving fluid from the outlet port (38) of the fermentor (18) to the inlet port (16 or 32) of the culture vessel (14).

With respect to claim 19, the device includes means (46) for removing fluid from the outlet port (40) of the culture vessel (14).

With respect to claims 24 and 38, in the absence of further positively recited structure, the bioreactor (14) of the reference of Besnainon et al. is considered to be a culture flask.

With respect to claims 25-27, elements (36) and (46) are pumps.

With respect to claims 36 and 37, the fermentor (18) includes a motor driven mixing paddle (20).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1744

10. Claims 20-23 and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Besnainon et al.(US 5,064,764).

The reference of Besnainon et al. has been discussed above.

With respect to claim 20, while the reference of Besnainon et al. discloses that the fermentor (18) includes a second outlet port (24) that is not connected to the culture vessel (14), the reference does not specifically disclose a means for moving fluid out of the fermentor and through the second port (24).

The reference of Besnainon et al. discloses that the second port (24) is for taking samples and is connected to an analyzer device (See column 4, lines 18-26). The use of pumps and/or valves for controlling the flow of a fluid through a conduit is known in the art as evidenced by pumps (30 and 36) in the system of Besnainon et al.

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to provide the outlet (24) of the system of Besnainon et al. with a pump device for the known and expected result of providing an art recognized means for controlling the flow of sample from the fermentor.

With respect to claim 21, the reference discloses reservoir (26) connected to an inlet port on the fermentor (See Figure 1) and a means (30) for removing medium from the reservoir to the inlet port of the fermentor.

With respect to claims 22 and 23, while the reference discloses only a single reservoir, inlet port and pump, the reference discloses that it is desirable to add glucose, glutamine or amino acids to the fermentor (See column 4, lines 23-26).

Art Unit: 1744

In the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide the system with individual vessels of glucose, glutamine and amino acids for the known and expected results of providing a means recognized in the art for allowing the control of the individual components of the medium added to the fermentor vessel.

With respect to claims 28-35, the reference discloses the use of pumps (30, 36, 46) for controlling the flow of fluid within the culture system.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,696,287. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not

Art Unit: 1744

identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 18-38 are generic to all that is recited in claims 1-21 of U.S. Patent No. 6,696,287. That is, claims 1-21 of U.S. Patent No. 6,696,287 fall entirely within the scope of instant claims 18-38 or, in other words, instant claims 18-38 are anticipated by claims 1-21 of U.S. Patent No. 6,696,287.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1744

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



William H. Beisner
Primary Examiner
Art Unit 1744

WHB